'08 CIV 4100

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

CAROL J. STRONG, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, MERCK & CO., INC., PROCTER & GAMBLE PHARMACEUTICALS, INC. and AVENTIS PHARMACEUTICALS, INC., Defendants.	Civil Action No. 08 CV COMPLAINT **JURY TRIAL DEMANDED**

Plaintiff Carol J. Strong ("Plaintiff"), by her attorneys, for her Complaint against defendants Novartis Pharmaceuticals Corporation ("Novartis"), Merck & Co., Inc. ("Merck"), Procter & Gamble Pharmaceuticals, Inc. ("P&GP") and Aventis Pharmaceuticals, Inc. ("Aventis") (jointly "Defendants"), alleges:

1. This is a civil action for damages suffered by Plaintiff as a result of her being prescribed and injected with Novartis' drugs Aredia and Zometa, being prescribed and ingesting Merck's drug Fosamax, and being prescribed and ingesting P&GP and Aventis' drug Actonel.

PARTIES

2. Plaintiff is a citizen and resident of the State of Montana, residing in Charlo, Montana.

3. At all times herein mentioned, Novartis was and is a Delaware corporation, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

4. At all times herein mentioned, Merck was and is a New Jersey corporation, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

5. At all times herein mentioned, Defendant P&GP was and is a Ohio corporation, with its principal place of business at One Proctor Gamble Plaza, Cincinnati, Ohio 45202-3393.

6. At all times herein mentioned, Defendant Aventis was and is a Delaware corporation, with its principal place of business at 200 Crossing Boulevard, Bridgewater, New Jersey 08807.

7. At all times herein mentioned, Defendants did business in the States of New York and Montana.

JURISDICTION

8. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars ($75,000.00) and Plaintiff is a citizen of a State which is different from the State where

defendants are incorporated and have their principal places of business.

FACTUAL BACKGROUND

9. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

10. Aredia is the brand name of pamidronate and Zometa is the brand name of zolodrenic acid, both are in a class of prescription drugs called bisphosphonates. Aredia and Zometa are administered intravenously and/or by injection.

11. Aredia and Zometa were approved by the United States Food and Drug Administration for treatment of hypercalcemia and bone matastases.

12. The product literature prepared by Novartis and circulated to physicians for use in prescribing the drugs contained no warning about osteonecrosis of the jaw or other bone structure.

13. In 2002 or before, Novartis received information from a physician that several of the physician's patients who were given Aredia were diagnosed with osteonecrosis of the jaw and that he believed a causal relationship existed between the use of Aredia and osteonecrosis of the jaw.

14. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after

being given Aredia and Zometa. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

15. Novartis sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of Aredia and Zometa in September 2004 and May 2005.

16. Plaintiff was prescribed and given Aredia and Zometa.

17. As a result of being given and/or injected with Aredia and Zometa, Plaintiff developed osteonecrosis of the jaw.

18. As a result of being given and/or injected with Aredia and Zometa Plaintiff suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe past and future pain and suffering;

c. severe past and future mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. past and future medical care and monitoring; and

g. loss of past and future income.

19. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.

20. Fosamax is the brand name of alendronate sodium, which is in a class of prescription drugs called bisphosphonates. Fosamax is taken orally.

21. Fosamax was approved by the United States Food and Drug Administration for treatment of osteoporosis.

22. The product literature prepared by Merck and circulated to physicians for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other bone structure.

23. In 2002 or before, Merck knew or should have known that a physician reported that several of his patients who were given Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw.

24. Merck never issued any warnings or changed its product literature to warn of the risk of osteonecrosis of the jaw.

25. Plaintiff was prescribed and took Fosamax.

26. As a result of taking Fosamax, Plaintiff developed osteonecrosis of the jaw.

27. As a result of taking Fosamax Plaintiff suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe past and future pain and suffering;

c. severe past and future mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. past and future medical care and monitoring; and

g. loss of past and future income.

28. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

29. Actonel is the brand name of risedronate sodium, which is in a class of prescription drugs called bisphosphonates. Actonel is taken orally.

30. Actonel was approved by the United States Food and Drug Administration for treatment of osteoporosis.

31. The product literature prepared by P&GP and Aventis and circulated to physicians for use in prescribing the drug

contained no warning about osteonecrosis of the jaw or other bone structure.

32. In 2002 or before, P&GP and Aventis knew or should have known that a physician reported that several of his patients who were given Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw.

33. P&GP and Aventis never issued any warnings or changed their product literature to warn of the risk of osteonecrosis of the jaw.

34. Plaintiff was prescribed and took Actonel.

35. As a result of taking Actonel, Plaintiff developed osteonecrosis of the jaw.

36. As a result of taking Actonel Plaintiff suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe past and future pain and suffering;

c. severe past and future mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. past and future medical care and monitoring; and

g. loss of past and future income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

37. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 36 of the Complaint as if they were set forth here in full.

38. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

39. Aredia and Zometa as designed, manufactured and sold by Novartis were defective in design or formulation in that they were unreasonably dangerous.

40. Aredia and Zometa as designed, manufactured and sold by Novartis were defective in design or formulation in that their foreseeable risks exceeded the benefits associated with the design or formulation.

41. Aredia and Zometa as designed, manufactured and sold by Novartis were defective due to inadequate warnings because Novartis knew or should have known that the products created a risk of harm to consumers.

42. Aredia and Zometa as designed, manufactured and sold by Novartis were defective due to inadequate testing.

43. As the proximate cause and result of the defective condition of Aredia and Zometa as designed, manufactured and sold by Novartis, Plaintiff was injured.

44. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.

45. Fosamax as designed, manufactured and sold by Merck was defective in design or formulation in that it was unreasonably dangerous.

46. Fosamax as designed, manufactured and sold by Merck was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

47. Fosamax as designed, manufactured and sold by Merck was defective due to inadequate warnings because Merck knew or should have known that the product created a risk of harm to consumers.

48. Fosamax as designed, manufactured and sold by Merck was defective due to inadequate testing.

49. As the proximate cause and result of the defective condition of Fosamax as designed, manufactured and sold by Merck, Plaintiff was injured.

50. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

51. Actonel as designed, manufactured and sold by P&GP and Aventis was defective in design or formulation in that it was unreasonably dangerous.

52. Actonel as designed, manufactured and sold by P&GP and Aventis was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

53. Actonel as designed, manufactured and sold by P&GP and Aventis was defective due to inadequate warnings because P&GP and Aventis knew or should have known that the product created a risk of harm to consumers.

54. Actonel as designed, manufactured and sold by P&GP and Aventis was defective due to inadequate testing.

55. As the proximate cause and result of the defective condition of Actonel as designed, manufactured and sold by P&GP and Aventis, Plaintiff was injured.

SECOND CLAIM FOR RELIEF

[Strict Product Liability - Failure To Warn]

56. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 36 of the Complaint as if they were set forth here in full.

57. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

58. Aredia and Zometa as designed, manufactured and sold by Novartis were not accompanied by proper warnings regarding possible adverse side effects.

59. Novartis knew or should have known about the possible adverse side effects of Aredia and Zometa, including osteonecrosis of the jaw.

60. As the proximate cause and result of Novartis' failure to properly warn physicians and consumers, Plaintiff was injured.

61. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.

62. Fosamax as designed, manufactured and sold by Merck was not accompanied by proper warnings regarding possible adverse side effects.

63. Merck knew or should have known about the possible adverse side effects of Fosamax, including osteonecrosis of the jaw.

64. As the proximate cause and result of Merck's failure to properly warn physicians and consumers, Plaintiff was injured.

65. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

66. Actonel as designed, manufactured and sold by P&GP and Aventis was not accompanied by proper warnings regarding possible adverse side effects.

67. P&GP and Aventis knew or should have known about the possible adverse side effects of Actonel, including osteonecrosis of the jaw.

68. As the proximate cause and result of P&GP and Aventis' failure to properly warn physicians and consumers, Plaintiff was injured.

THIRD CLAIM FOR RELIEF

[Negligence]

69. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 36 of the Complaint as if they were set forth here in full.

70. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

71. Novartis had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia and Zometa, including a duty to assure that users, like Plaintiff, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

72. Novartis failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia and Zometa in that Novartis knew or should have known that Aredia and Zometa created an unreasonable risk of osteonecrosis of the jaw.

73. Novartis was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia and Zometa.

74. As the proximate cause and result of Novartis' negligence, Plaintiff was injured.

75. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.

76. Merck had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax, including a duty to assure that

users, like Plaintiff, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

77. Merck failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax in that Merck knew or should have known that Fosamax created an unreasonable risk of osteonecrosis of the jaw.

78. Merck was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax.

79. As the proximate cause and result of Merck's negligence, Plaintiff was injured.

80. P&GP and Aventis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

81. P&GP and Aventis had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel, including a duty to assure that users, like Plaintiff, did not suffer unreasonable adverse side P&GP and Aventis failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel in that P&GP and Aventis knew or

should have known that Actonel created an unreasonable risk of osteonecrosis of the jaw.

82. P&GP and Aventis were negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel.

83. As the proximate cause and result of P&GP and Aventis' negligence, Plaintiff was injured.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

84. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 36 of the Complaint as if they were set forth here in full.

85. Novartis expressly warranted, by and through statements made by Novartis or its authorized agents, that Aredia and Zometa were safe, effective, and fit for their intended uses.

86. Plaintiff, and her agents, relied on the skill, judgment and representations of Novartis.

87. Aredia and Zometa did not conform to Novartis' express warranties in that they were not safe and fit for their intended uses because they caused serious adverse side effects, including osteonecrosis of the jaw.

88. As the proximate cause and result of Novartis' breach of its express warranties, Plaintiff was injured.

89. Merck expressly warranted, by and through statements made by Merck or its authorized agents, that Fosamax was safe, effective, and fit for its intended use.

90. Plaintiff, and her agents, relied on the skill, judgment and representations of Merck.

91. Fosamax did not conform to Merck's express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

92. As the proximate cause and result of Merck's breach of its express warranties, Plaintiff was injured.

93. P&GP and Aventis expressly warranted, by and through statements made by P&GP and Aventis or their authorized agents, that Actonel was safe, effective, and fit for its intended use.

94. Plaintiff, and her agents, relied on the skill, judgment and representations of P&GP and Aventis.

95. Actonel did not conform to P&GP Aventis' express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

96. As the proximate cause and result of P&GP and Aventis' breach of their express warranties, Plaintiff was injured.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

97. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 36 of the Complaint as if they were set forth here in full.

98. Novartis impliedly warranted to Plaintiff, and her agents, that Aredia and Zometa were of merchantable quality and were safe and fit for their intended uses.

99. Plaintiff, and her agents, relied on Novartis' skill and judgment.

100. Aredia and Zometa were not of merchantable quality or safe and fit for their intended uses in that they caused serious adverse side effects, including osteonecrosis of the jaw.

101. As the proximate cause and result of Novartis' breach of its implied warranties, Plaintiff was injured.

102. Merck impliedly warranted to Plaintiff, and her agents, that Fosamax was of merchantable quality and was safe and fit for its intended use.

103. Plaintiff, and her agents, relied on Merck's skill and judgment.

104. Fosamax was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

105. As the proximate cause and result of Merck's breach of its implied warranties, Plaintiff was injured.

106. P&GP and Aventis impliedly warranted to Plaintiff, and her agents, that Actonel was of merchantable quality and was safe and fit for its intended use.

107. Plaintiff, and her agents, relied on P&GP and Aventis' skill and judgment.

108. Actonel was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

109. As the proximate cause and result of P&GP and Aventis' breach of its implied warranties, Plaintiff was injured.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Carol J. Strong respectfully prays for relief and judgment against the Defendants as follows:

(a) compensatory damages in an amount to be determined at trial;

(b) attorneys' fees, expenses, and costs of this action; and

(c) for any other relief this Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Dated: New York, New York
May 1, 2008

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